

REMARKS

Favorable reconsideration of this application is respectfully requested in view of the foregoing amendments and following remarks. Claims 27 - 32, and 34 are pending in this application.

The specification has been amended to identify U.S. Patent No. 6,355,245, which is the issued patent corresponding to the U.S. application identified and incorporated by reference into the specification at page 8. The specification also has been amended at page 8 to identify hybridoma h5G1.1 (ATCC HB 11625), a hybridoma which produces the h5G1.1 antibody. The specification also has been amended to include a Sequence Listing (in both computer readable form and in a paper copy, the content of the paper copy and the computer readable form being the same and including no new matter) containing the sequences of several versions of the h5G1.1-scFv antibody. Specifically, SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16 and 18 presented in the sequence listing (which correspond to SEQ ID. NOs: 8, 17, 20, 21, 22, 23, 24, 25 and 26 of U.S. Patent No. 6,355,245) are versions of the h5G1.1-scFv antibody. Because the hybridoma and the sequences are described in U.S. Patent No. 6,355,245, and the entire content of U.S. Patent No. 6,355,245 has been incorporated by reference into the present application, these amendments to the specification introduce no new matter.

In the Office Action of June 3, 2005, (the "Office Action"), Claims 27-41 were rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Office Action asserts that the claims have limitations which are not disclosed in the specification and therefore constitute new matter.

Specifically, the Office Action asserts claim 27 recites a method comprising "a first step of administering an anti-inflammatory agent prior to or at the start of surgery and a second step of administering an anti-inflammatory agent subsequent to the start of surgery. Claim 36 recites that the method comprises a single step of administering an anti-inflammatory agent prior to or at the start of surgery." The Office Action goes on to assert that the dependent claims only set forth concentrations and the nature of the anti-inflammatory compound, which the Office Action asserts is limited to "antibodies to complement components or to proteins associated with the complement system."

Applicants respectfully submit that this rejection is in error and should be withdrawn. With respect to the assertion that the specification fails to teach administering an anti-inflammatory agent prior to or simultaneously with the start of surgery, or administering additional anti-inflammatory agent subsequent to the start of surgery, it seems that the Example beginning on page 8 of the specification has been completely ignored or overlooked. This example sets forth exactly a method in accordance with the claims. (See, e.g., page 9, lines 2-6, which states as follows: "Patients received the bolus of study medication ten (10) minutes before the initiation of cardio-pulmonary bypass via a unique line. The drug was not to be combined with other medication given via this route. The infusion began immediately following bolus administration, and continued for 24 hours at a constant drip rate".) Moreover, with respect to anti-inflammatory agents, it appears that page 5, lines 7-21 of the specification, which lists numerous anti-inflammatory agents, has been overlooked.

(With respect to the rejection of Claim 36, that Claim has been cancelled, rendering moot this rejection.)

Thus, it is respectfully submitted there is sufficient support for the currently pending claims, i.e., claims 27-32 and 34, and this rejection should thus be withdrawn.

Claims 32 and 41 were rejected under 35 U.S.C. §112, first paragraph, as not being enabled. The Office Action asserts that the hybridoma cell line must be available, such as by a cell line deposit. Such a deposit was in fact made prior to the effective filing date of the instant application and the specification has been amended to reflect such a deposit. Enclosed please find as Exhibit A a copy of a deposit form from the American Type Culture Collection for ATCC Designation HB 11625, showing a deposit on April 29, 1994 of the hybridoma cell line which produces a whole antibody h5G1.1. Manufacturing the single-chain antibody h5G1.1– scFv is taught by U.S. Patent No. 6,355,245 and by the Thomas et al. publication as described on page 8 of the present application, the entire disclosures of each of which have been incorporated by reference into the specification as filed at page 8 thereof. Also, Exhibit hereto B is a copy of a letter sent by applicants' representatives on February 3, 2003 to the ATCC asking that this deposit be released according to the Budapest Treaty, demonstrating that the deposit is publicly available. In view of the foregoing, it is respectfully submitted that this rejection should be withdrawn.

Finally, claims 32 and 41 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for use of the name "h5G1.1 – scFv" for the antibody. Several protein sequences of this antibody are presented as SEQ ID NOs: 8, 17, 20,


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Reply to Office Action dated June 3, 2005

21, 22, 23, 24, 25 and 26 in U.S. Patent No. 6,355,245, the entire contents of which have been incorporated by reference into the present application.

Claim 32 has been amended to refer to SEQ ID NOs: 2, 4, 6, 8, 10 12, 14, 16 and 18 instead of using the name h5G1.1 – scFv. The protein sequences shown as SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, and 18 of the instant application are identical to SEQ ID NOs: 8, 17 and 20-26 of U.S. Patent No. 6,355,245. Accordingly, it is respectfully requested that this rejection be withdrawn.

In view of the foregoing, this application is believed to be in condition for allowance. Such early and favorable action is earnestly solicited.

Respectfully submitted,



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MRB/jjp



American Type Culture Collection

12361 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301) 231-5520 Telex: 898-855 ATCCNORTH • FAX: 301-770-2587

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Dr. Seth Fidel
Alexion Pharmaceuticals, Inc.
25 Science Park, Suite 380
New Haven, CT 06511

Deposited on Behalf of: Alexion Pharmaceuticals, Inc., Dr. Eileen Elliot Mueller, Dr.
Scott Rollins, and Dr. Stephen Squinto

Identification Reference by Depositor:

ATCC Designation

Hybridoma, 5G1.1

HB 11625

The deposit was accompanied by: ☐ a scientific description ☐ a proposed taxonomic
description indicated above.

The deposit was received April 27, 1994 by this International Depository Authority
and has been accepted.

AT YOUR REQUEST:

☒ We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty
certifies one's right to receive, or if a U.S. Patent is issued citing the strain.

If the culture should die or be destroyed during the effective term of the deposit, it
shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years after the date of deposit,
and for a period of at least five years after the most recent request for a sample. The
United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested April 29, 1994. On that date, the
culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md.
20852 USA

Signature of person having authority to represent ATCC:

Bobbie A. Brandon
Bobbie A. Brandon, Head, ATCC Patent Depository

Date: May 2, 1994

cc: Maurice Klee

Form BP4/9

BEST AVAILABLE COPY



Stephen A. Saxe, Ph.D.
Counsel, Intellectual Property

saxes@alxn.com

February 3, 2003

VIA FACSIMILE

Marie Harris
American Type Culture Collection (ATCC)
P.O. Box 1549
Manassas, VA 20108

Dear Ms. Harris:

We are requesting that ATCC release according to the Budapest Treaty the hybridoma cell line that is ATCC Designation HB 11625. This cell line was deposited in 1994 for patent purposes. U.S. Patent No. 6,355,245 claiming the hybridoma issued on March 12, 2002. For your reference, attached is a copy of Form BP4/9 that was sent to Alexion Pharmaceuticals, Inc. in 1994 as a receipt of the deposit.

The deposit for HB 11625 was made in 1994 and the attorneys handling Alexion's patent portfolio at that time were Seth Fidel and Maurice Klee, both of whom are listed on Form BP4/9. Since that time there has been a change in patent attorneys and also a change in the address of Alexion Pharmaceuticals. Please send all future correspondence concerning this matter to:

Stephen A. Saxe, Ph.D.
Counsel, Intellectual Property
Alexion Pharmaceuticals, Inc.
352 Knotter Drive
Cheshire, CT 06410
Tel. 203-271-8289
Fax 203-271-8195
E-mail saxes@alxn.com

Please inform me if anything further is required to have the hybridoma released or if you require any further information from Alexion Pharmaceuticals.

Very truly yours,

Stephen A. Saxe